Report SAM-TR-76-4

THE BIOLOGICAL SIGNIFICANCE OF RADIOFREQUENCY RADIATION EMISSION ON CARDIAC PACEMAKER PERFORMANCE

January 1976

Interim Report for Period January - August 1975

USAF SCHOOL OF AEROSPACE MEDICINE
Aerospace Medical Division (AFSC)
Brooks Air Force Base, Texas 78235

NOTICES

This interim report was submitted by personnel of the Radiation Physics Branch, Radiobiology Division, USAF School of Aerospace Medicine, Aerospace Medical Division, AFSC, Brooks Air Force Base, Texas, under job order 7757-01-46.

When U.S. Government drawings, specifications, or other data are used for any purpose other than a definitely related Government procurement operation, the Government thereby incurs no responsibility nor any obligation whatsoever; and the fact that the Government may have formulated, furnished, or in any way supplied the said drawings, specifications, or other data is not to be regarded by implication or otherwise, as in any manner licensing the holder or any other person or corporation, or conveying any rights or permission to manufacture, use, or sell any patented invention that may in any way be related thereto.

This report has been reviewed by the Information Office (OI) and is releasable to the National Technical Information Service (NTIS). At NTIS, it will be available to the general public, including foreign nations.

This technical report has been reviewed and is approved for publication.

John C Mitchell
JOHN C. MITCHELL, B.S.
Project Scientist

John E. Pickering
JOHN E. PICKERING, M.S.
Supervisor

Robert G. McIver
ROBERT G. MCIVER, Colonel, USAF, MC
Commander

UNCLASSIFIED
SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

REPORT DOCUMENTATION PAGE	READ INSTRUCTIONS BEFORE COMPLETING FORM
1. REPORT NUMBER: SAM-TR-76-4 (14)	2. GOVT ACCESSION NO.
	3. RECIPIENT'S CATALOG NUMBER (9)
4. TITLE (and Subtitle): THE BIOLOGICAL SIGNIFICANCE OF RADIO-FREQUENCY RADIATION EMISSION ON CARDIAC PACEMAKER PERFORMANCE. (6)	5. TYPE OF REPORT & PERIOD COVERED: Interim rept. January — August 1975
	6. PERFORMING ORG. REPORT NUMBER
7. AUTHOR(s): John C. Mitchell, B.S. (10) William D. Hurt, M.S.	8. CONTRACT OR GRANT NUMBER(s)
9. PERFORMING ORGANIZATION NAME AND ADDRESS: USAF School of Aerospace Medicine (RAP) Aerospace Medical Division (AFSC) Brooks Air Force Base, Texas 78235	10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS: 62202F 7757-01-46
11. CONTROLLING OFFICE NAME AND ADDRESS: USAF School of Aerospace Medicine (RAP) Aerospace Medical Division (AFSC) Brooks Air Force Base, Texas 78235 (11)	12. REPORT DATE: January 1976 (12) 23 p.
	13. NUMBER OF PAGES: 19
14. MONITORING AGENCY NAME & ADDRESS(if different from Controlling Office): (16) AF-7757 (17) 775701	15. SECURITY CLASS (of this report): Unclassified
	15a. DECLASSIFICATION DOWNGRADING SCHEDULE

16. DISTRIBUTION STATEMENT (of this Report)

Approved for public release, distribution unlimited.

DDC RECEIVED APR 13 1976 D

17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)

18. SUPPLEMENTARY NOTES

19. KEY WORDS (Continue on reverse side if necessary and identify by block number)

Cardiac pacemaker interference
EMC, EMI
Radiofrequency radiation effects

20. ABSTRACT (Continue on reverse side if necessary and identify by block number)

The effect of radiofrequency (RF) radiation emission on cardiac pacemaker function is a unique bioeffects phenomenon. Dependent on the pacemaker type and design, and on the frequency, peak E-field intensity, pulse width, and effective pulse repetition rate of the incident RF signal, the pacemaker may cut off completely, revert to a fixed interference-rejection mode of operation, experience intermittent disruption, or be totally unaffected. Experimental evidence is presented for a wide variety of tests conducted under controlled →

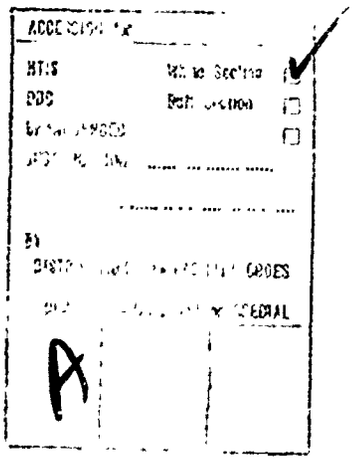
DD FORM 1 JAN 73 1473 EDITION OF 1 NOV 65 IS OBSOLETE

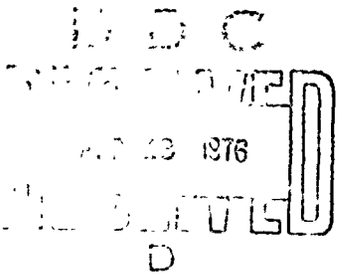
317000 V

UNCLASSIFIED
SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

20. ABSTRACT (Continued)

laboratory conditions and in the vicinity of numerous types of RF emitters prevalent in U.S. population centers. These test results are discussed in terms of their clinical significance, technical feasibility of designing pacemakers to avoid electromagnetic interference, and appropriate design goals to achieve overall RF environmental compatibility.





THE BIOLOGICAL SIGNIFICANCE OF RADIOFREQUENCY RADIATION EMISSION ON CARDIAC PACEMAKER PERFORMANCE

INTRODUCTION

During the past 10 years, the electronic cardiac pacemaker has been developed into a sophisticated prosthetic device. It is applied in medical facilities throughout the world to correct malfunctions (atrioventricular heart block) of the body's electrical conduction system and thus to restore the rhythmic pumping action of the heart.

Pacemakers may be classed as fixed rate (asynchronous) and demand (synchronous or R-wave inhibited). Fixed-rate pacemakers provide a fixed, preset rate of electrical stimuli to the ventricles, which is independent of the electrical and/or mechanical activity of the heart. Demand pacemakers sense the depolarizations of the heart muscle activity and produce their own depolarization signals (electrical stimulus) only if the normal heart depolarizations are not present. The atrial synchronous pacemakers sense the depolarization of the atria, delay the signal to simulate natural conduction time, and then provide the electrical stimulus to the ventricles. The R-wave inhibited demand pacemaker inhibits its output when it senses depolarization of the ventricles if it occurs naturally; i.e., the pacemaker functions only when the AV heart block occurs (11).

Most pacemakers implanted today are the R-wave inhibited type. They contain an electronic timing circuit which is reset by normal depolarization or the pacemaker stimulus. Their sensing circuit is programmed to respond to electrical signals normally generated by the heart. Energy pulses induced externally via the pacemaker leads or circuitry can erroneously cause the pacemaker to inhibit its needed output (4, 8). Thus, the interaction of radiofrequency (RF) electromagnetic radiation fields with cardiac pacemakers represents a unique indirect biological effect. This results primarily from the fact that current pacemaker interference thresholds begin as low as 10 V/m, while peak E-field levels of several hundred volts per meter can be associated with pulsed fields having average power densities well below the acceptable, nonrestricted 10 mW/cm^2 personnel exposure level; i.e., the E-field level of a continuous wave (CW) 10 mW/cm^2 field is about 200 V/m, but it can be much higher for a low duty cycle pulsed source, having the same 10 mW/cm^2 average power density.

Case histories of pacemaker electromagnetic interference (EMI) reported in the open literature (1, 5, 6, 9, 10, 12, 15), combined with

newer findings such as those discussed at the June 1975 FDA open public hear ng on pacemaker interference by antitheft devices, substantiate the potential problem. Also, many cases of pacemaker EMI probably go unreported due to the nature of the interference phenomena. For instance, upon sensing intense 60-Hz external EM radiation, many pacemakers revert to a fixed rate so close to their demand rate that the user would not normally detect the change. Radiofrequency radiation emitters such as air route surveillance radar can cause many pacemakers to miss single beats as the radar beam scans past, an effect most likely unnoticed (8). Even more serious interference may not be identified because, most often, interaction times are short; i.e., either the source of EMI is moved or turned off or the user moves from the particular area of the effect. Additionally, little postmortem followup is available to identify any possible causal relationship to EMI.

Although the potential hazard to individual users of the more sensitive pacemakers is generally acknowledged, controversy will continue as to the clinical significance of this effect of RF radiation on the pacemaker populace (2, 14).

Results of tests conducted in 1974 and 1975 by the USAF School of Aerospace Medicine (USAFSAM), both in the USAFSAM RF laboratory and in close proximity to a series of Air Force RF emitters, demonstrate the significance of EM emission characteristics in the overall assessment of the EMI of cardiac pacemakers.

TEST PROCEDURES

Implant Simulation

Realistic assessment of the effects of radiofrequency electromagnetic radiation (EMR) on cardiac pacemakers requires actual implant conditions or accurate simulation of implantation. Initial EMI studies by USAFSAM were conducted by implanting pacemakers in 18-to 20-kg dogs and effecting a complete atrioventricular heart block (18). This procedure is costly and has obvious disadvantages in having to handle the animals under a variety of test conditions in the laboratory and at remote test sites. Thus, alternate techniques were developed to simulate the pacemaker implant (4, 7, 8).

More recently the Association for the Advancement of Medical Instrumentation (AAMI), working under a contract with the U.S. Food and Drug Administration (FDA), has developed a draft protocol for testing cardiac

pacemaker EMI characteristics. They recommend using a 80- x 40- x 20-cm container made of 5-cm-thick, low-dielectric plastic foam (density of 0.035 g/cm^3). The container is filled with 0.03 molar saline solution, and the pacemaker leads are located to place 1 cm of solution between the pacemaker and its lead(s) and the wall of the container. The pacemaker lead is stretched out horizontally, and the pacemaker response is picked up via 2- x 2-cm copper-mesh screen electrodes placed in the solution in each end of the container. The USAFSAM pacemaker test container used in the laboratory studies reported herein was designed to AAMI specifications and is shown in Figure 1. For purposes of this illustration, the front view of the container shows the pacemaker placed outside the test container. During testing, the pacemaker and horizontal lead arrangement is placed inside the test container as described above, with 1 cm of solution between the pacemaker and front wall of the container. A similar arrangement used in all previous USAFSAM tests provided good correlation between this method of simulated implant and the implanted dogs (4, 18). With the many variables (body size, location, orientation, depth of implant) in actual human implants, this procedure for implant simulation is believed sufficient for EMI testing. Additionally, it is recommended that both "free-field" and "simulated-implant" data be reported to bracket actual implant representation.

Instrumentation

Many different types of instrumentation techniques have been used in cardiac pacemaker EMI testing (4, 8, 15-18). The principal requirement is that the instrumentation system be immune to the EM fields encountered in the tests and that it presents to the pacemaker a load and signal simulating those encountered in an actual implant situation, so that the results obtained apply to a human implant. The system should also provide simultaneous real-time recording of the incident EMR signal and the pacemaker response.

Several pacemaker models have interference rates identical to their demand rates, so it is often difficult to determine susceptibility thresholds for pacemakers in EMR fields having pulse repetition rates (PRR) sufficient to cause the pacemaker to revert to its fixed rate. The minimum PRR values range from 3 to 60 Hz depending on the specific pacemaker. Thus, a device to simulate normal heart activity at the pacemaker leads is required so that an R-wave inhibited pacemaker would be inhibited by this simulated activity and would not produce a pulse until it detected interference and reverted to its interference mode. An additional requirement is imposed for a synchronous pacemaker to track the simulated activity up to its interference threshold. A system

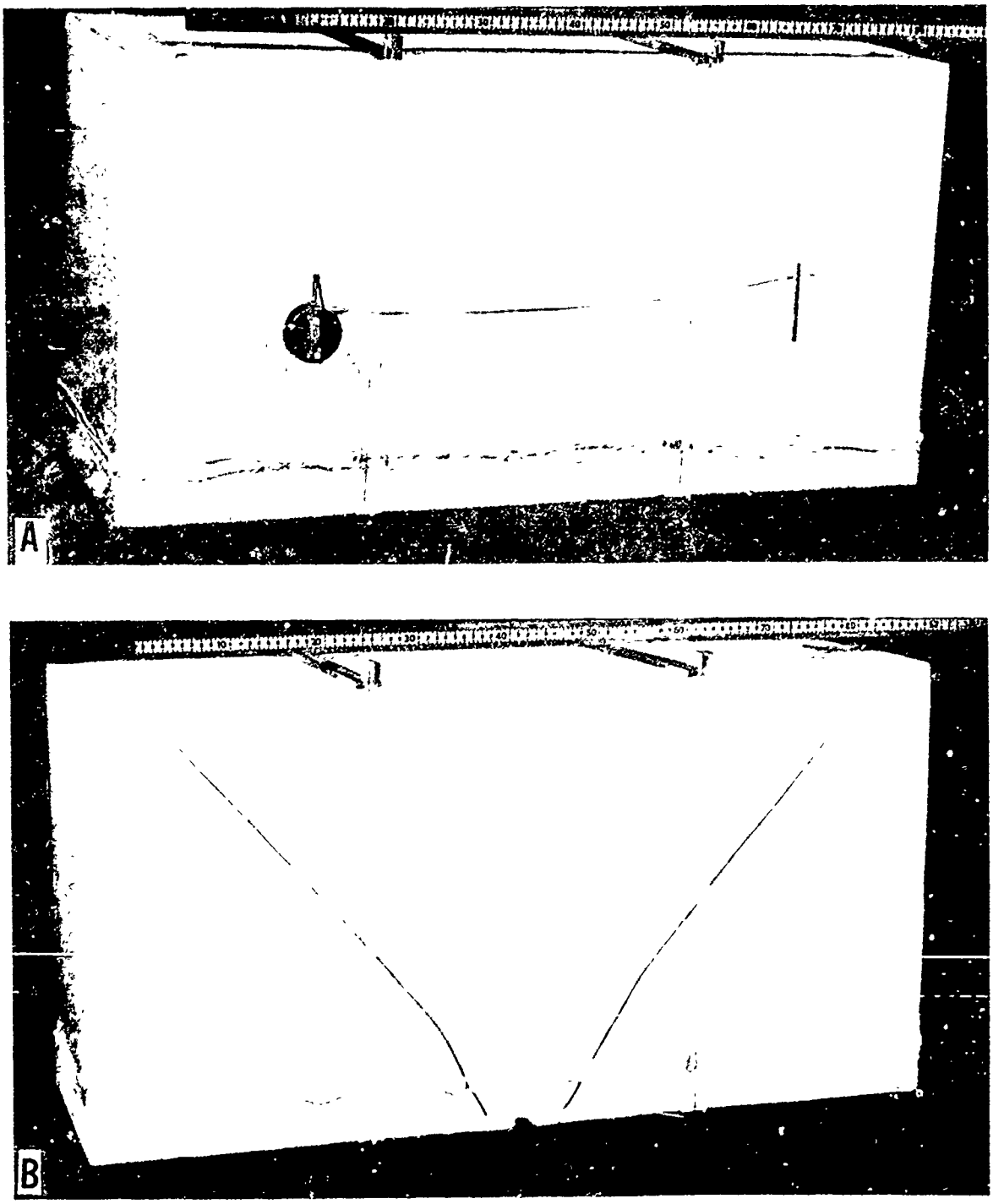


Figure 1. USAFSAM testing container used in pacemaker EMI tests.
A: Front view. B: Back view.

of this type has been developed and incorporates a light-emitting diode (LED) fiber optics monitoring system (16). This system was used in essentially all of the field tests at RF emitter sites. Results of such tests are in good agreement with USAFSAM laboratory studies using the AAMI-type test arrangement as described above.

TEST RESULTS

Laboratory Studies

Eighty pacemakers (23 different models) were evaluated to establish their relative electromagnetic interference (EMI) susceptibilities as a function of the radiation frequency, pulse width, and E-field intensity. Figure 2 shows most of the pacemaker types tested. The tests were

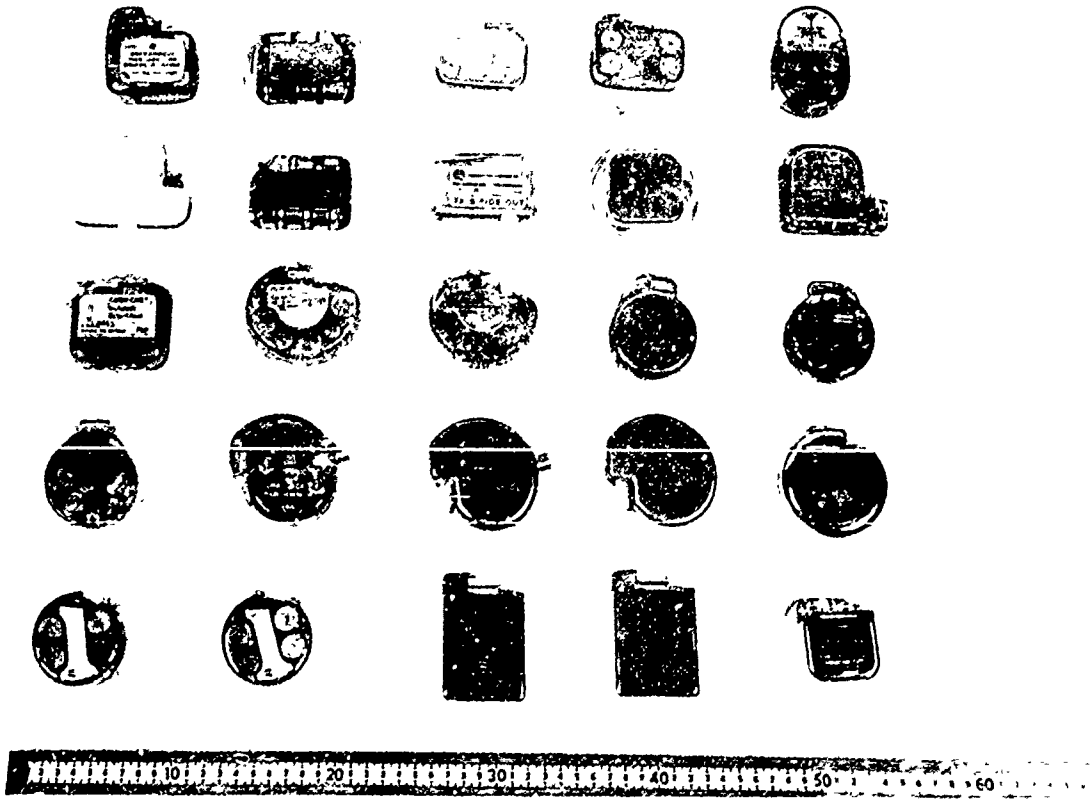


Figure 2. Pacemaker models representative of those tested.

performed in the USAFSAM RF anechoic chamber using three different frequencies (450, 1600, and 3200 MHz); a constant pulse repetition rate of 10 pulses per second (pps); pulse widths (duration) of 0.01, 0.02, 0.5, 1, 2, 5, 10, and 20 ms; and E-field levels up to 1200 V/m. The total ranges of pulse widths (PW) and E-field levels were somewhat different for each frequency.

The 450-MHz radiation source was provided by Microwave Cavity Laboratory (MCL) model 15022 power generator, amplified by an MCL model 10110 power amplifier (up to 1000 W), and fed via an air dielectric "Heliax" transmission line to an EMCO model 3101 conical logspiral antenna

The 1600- and 3200-MHz radiation sources were provided by a Cober model 1831 high-power microwave generator (peak power up to 1800 W). The 1600-MHz signal was fed via a 7/8" air dielectric "Heliax" transmission line to an AEL model H-5001 horn in the anechoic chamber. The 3200-MHz signal was fed via flexible waveguide to a Struthers model 1109 antenna horn.

A multiple-pulse generator designed and built at USAFSAM to supply external modulation for both the MCL and Cober generators was used to provide the special pulse modulation used in these tests.

Figure 3 shows the antenna and test container configuration in the anechoic chamber for the 450-MHz tests. Similar arrangements were used for the 1600- and 3200-MHz tests. Figure 4 illustrates the test arrangement and monitoring system used. Many of the pacemakers were tested on both sides; i.e., after a set of data was collected, the pacemaker was turned over with its other side facing the incident radiation field. This can change some pacemaker thresholds by a factor of 2-3.

The RF field at the test location was measured (mapped) with a National Bureau of Standards (NBS) electric field intensity meter (model EDM-1B) and/or a Narda electromagnetic radiation monitor (model 8316). Less than 3-dB variation in the field was measured across the front of the pacemaker test container. The solution was then added to the container and the transmitter output power adjusted to equal that used for the field mapping measurements. A corresponding field measurement was made using a Singer field intensity analyzer (model EMA-910) or a Fairchild interference analyzer (model EMC-25) to establish a correlation factor between the field analyzer readings and the power density at the test location. The field analyzer was connected to a monitoring antenna which was located above and behind the pacemaker test container.

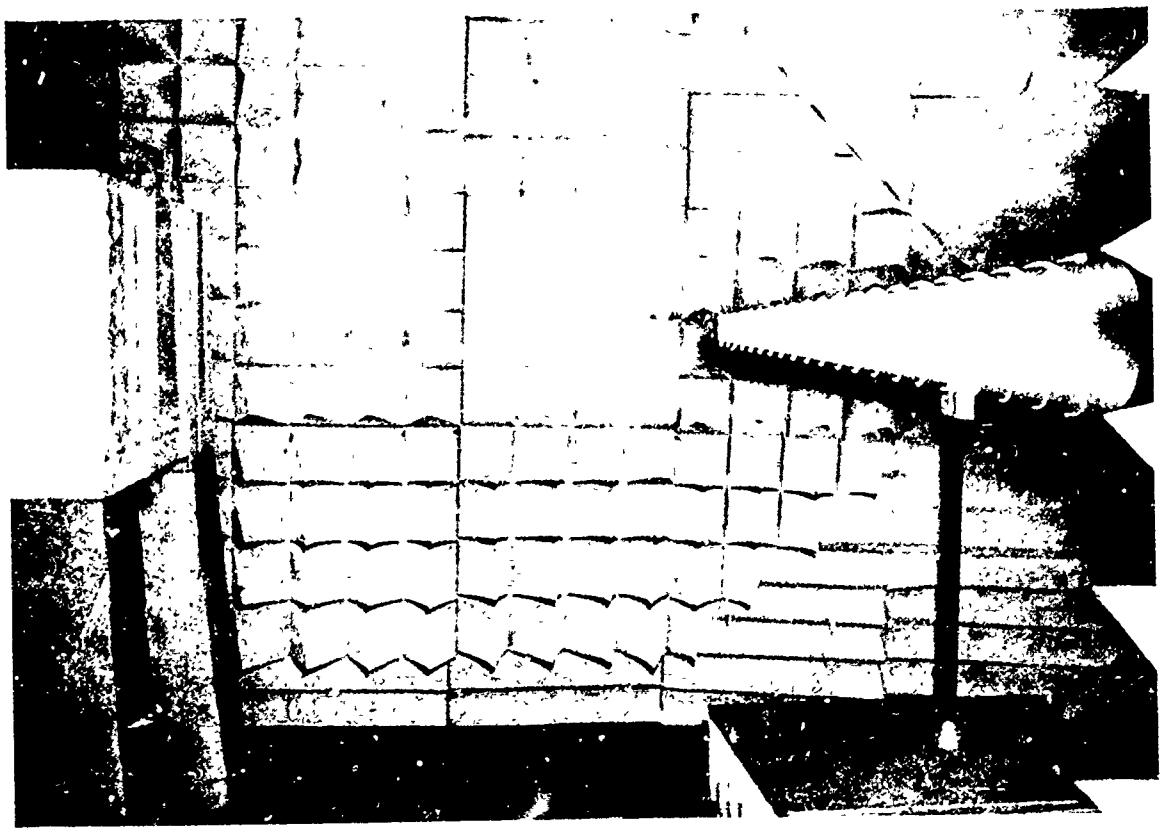


Figure 3. Pacemaker test configuration in the USAFSAM anechoic chamber.

The copper-mesh electrodes in the solution were connected to an ECG amplifier by approximately 10 ft of lossy line, and the signal conductor was routed via a shielded path through the anechoic chamber wall. The amplifier output was fed into a computing counter so that the pacemaker rate could be displayed, and also to one channel of a dual-channel strip-chart recorder. The field intensity analyzer output was recorded on the second channel.

The EMI threshold data obtained under simulated-implant conditions are summarized in Table 1 for each of the pacemaker types (models) tested. Where more than one of a particular model was evaluated, the lowest threshold value is presented because it is believed such values are sufficiently representative of the threshold value of these devices

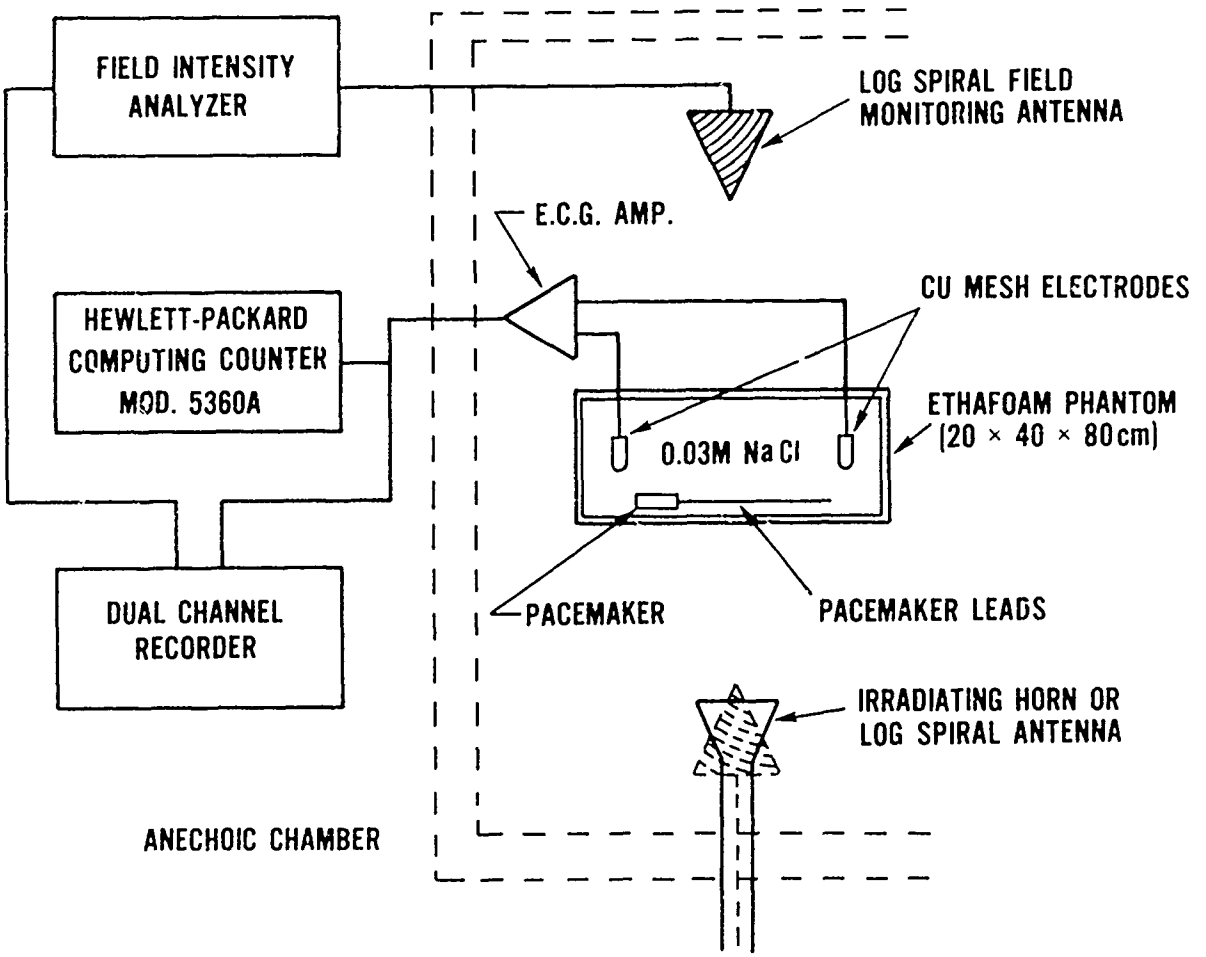


Figure 4. Schematic of pacemaker test configuration and monitoring instrumentation.

in use. The EMI threshold value in rms volts per meter represents the E-field strength at which the pacemaker rate falls below 50 beats per minute (bpm) or exceeds 120 bpm--arbitrarily defined here as a clinically significant adverse effect. Although essentially all these data were obtained for a constant pulse repetition rate of 10 pps, the PRR was occasionally decreased to confirm the interference threshold. This is necessary for this test configuration for pacemakers that remain in their fixed interference-rejection mode at a PRR of 10 pps, but that cut off when the PRR is lowered further.

TABLE 1. CARDIAC PACEMAKER EMI THRESHOLDS IN VOLTS/METER AS A FUNCTION OF FREQUENCY AND PULSE WIDTH (SIMULATED-IMPLANT; PULSE REPETITION RATE, 10 PPS)

	450 MHz Pulse width			1600 MHz Pulse width		3200 MHz Pulse width	
Pacemaker	20 ms	1 ms	10 μs	1 ms	2 μs	1 ms	2 μs
American Optical							
281003	6	13	62	132	623	620	>1200
281013	6	15	73	---	---	790	>1200
281143	>260	>260	>260	>725	---	>1200	---
Biotronik							
IDP-44	116	130	>260	>725	---	>1200	---
Cardiac Pacemaker							
301UD	>260	>260	>260	---	---	---	---
401BD	>260	>260	>260	---	---	---	---
Cordis							
Atricor 133C7[a]	18	19	28	35	148	642	>1200
Stanicor 143E7	15	13	65	83	380	400	>1200
Omni Atri. 164A[a]	9	12	110	---	---	>1200	---
Omni Stan. 162C	4	6	65	70	536	657	>1200
General Electric							
A2072D[b]	16	28	---	188	363	790	>1200
A2075A[b]	31	82	260	130	543	983	>1200
Medcor							
3-70A	23	23	46	34	209	325	>1200
Medtronic							
5942	37	39	260	>725	---	>1200	---
5944	82	110	>260	251	758	>1200	---
5950	>260	>260	>260	>725	---	>1200	---
5951	>260	>260	>260	>725	---	>1200	---
9000	22	26	>260	>725	---	>1200	---
Pacesetter							
BD-101	>260	>260	>260	>725	---	>1200	---
Starr-Edwards							
8114	14	21	---	56	139	357	>1200
8116	>260	>260	>260	>725	---	>1200	---
Stimtech							
3821	26	78	>260	199	536	>1200	---
Vitatron							
MIP-40-2T	37	116	207	226	623	579	>1200

NOTE: The maximum E-field levels available were 260, 725, and 1200 V/m for the 450, 1600, and 3200 MHz frequencies, respectively.

[a] These EMI thresholds represent the E-field level at which these cardiac pacemakers begin to synchronize with the incident RF signal; however, under worst-case conditions of these tests, these pacemakers did not exceed the manufacturer's design limits to ~150 bpm.

[b] These EMI thresholds were observed at 5 pps; at 10 pps the General Electric pacemakers generally revert to fixed rate.

These test results demonstrate that cardiac pacemaker EMI is strongly dependent on the frequency and pulse width of the incident radiation, and there remains a wide range of EMI thresholds among the different manufacturers and pacemaker models currently marketed. Of the three frequencies used, the 450-MHz source resulted in the lowest EMI thresholds. Data were obtained for about eight different pulse widths, but only the range is presented here to illustrate the general trend--that shorter pulse widths will result in higher EMI thresholds. Although the longest duration pulse used in these tests was 20 ms at the 450-MHz frequency, there is some indication that pulses wider than 20-30 ms may reverse the trend of EMI threshold values in some models of pacemakers (13).

In these tests, the antenna horns were placed with the E-field vector parallel to the horizontal lead arrangement for maximum coupling of RF to the pacemaker. Some pacemakers have better case attenuation and lead RF filtering, causing their EMI thresholds to shift more than others as the incident RF frequency is increased.

Five of the 11 manufacturers have essentially resolved the potential EMI problem, demonstrating the technical feasibility of developing cardiac pacemakers to be compatible with the overall RF environment. Progress in this respect has been remarkable compared with the EMI state of technology 3 years ago.

Field Test Studies

Tests were conducted in close proximity to a variety of RF radiation sources to assess potential EMI effects as a function of E-field level and corresponding distance from the respective emitters.

The emitter characteristics ranged in operating frequencies from 35 kHz to 9 GHz, pulse widths (PW) from 1 to 2000 μs, pulse repetition rates from 20 to 400 pps, and peak output powers from 0.02 to 32 MW.

Figure 5 illustrates the instrumentation system used in these field-test studies. In each instance, a vehicle was instrumented to accommodate the equipment necessary to monitor and record the real-time E-field level and cardiac pacemaker response on a dual-channel strip-chart recorder. For each test location, the pacemaker test container and field monitoring antenna were located 20-25 ft from the test vehicle.

The specific test equipment used to measure E-field exposure levels varied, depending on the electromagnetic frequency which was being

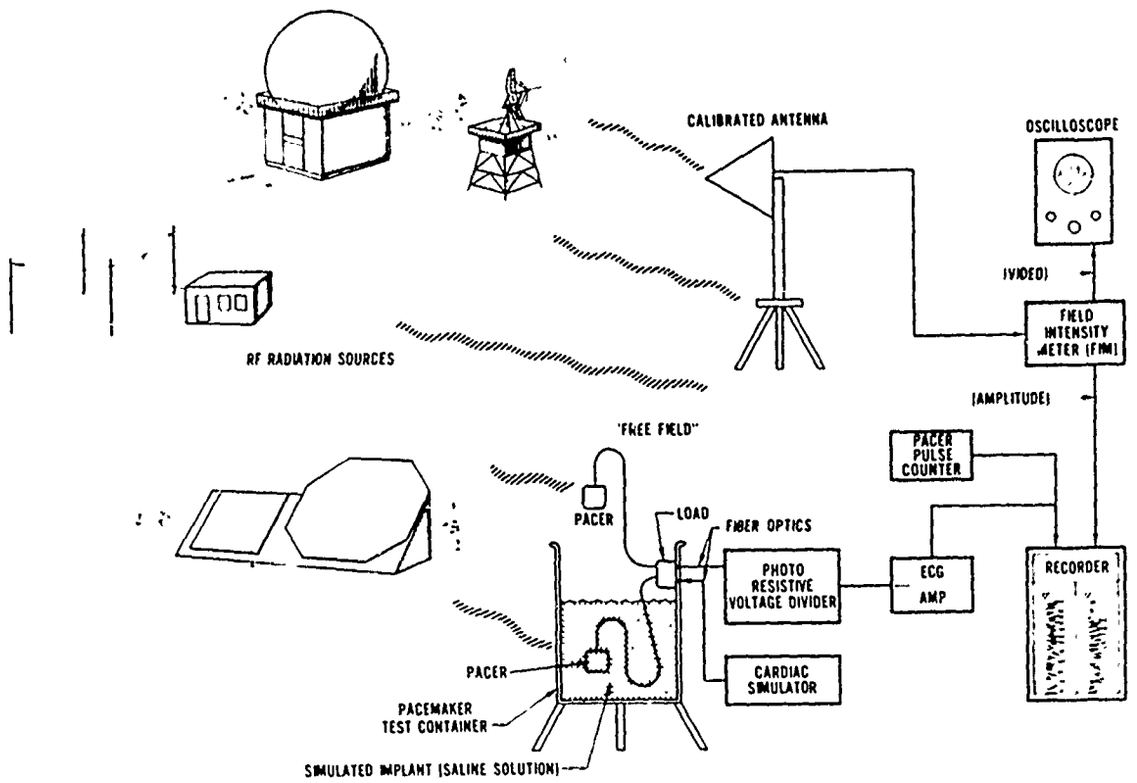


Figure 5. Instrumentation system for cardiac pacemaker EMI field tests.

measured. In general, this equipment consisted of a field intensity meter (FIM), associated calibrated antennas, and a strip-chart recorder. The FIM is an internally calibrated receiver capable of measuring amplitudes of electromagnetic energy at the FIM input. Applying known calibration factors for the respective antenna enables an operator to measure the field intensity at the antenna. The field intensity in this study is referred to as the E-field level. An oscilloscope was intermittently used to observe the pulse rate and width of the incident signal (RF radiation).

To assure maximum accuracy, pulse and signal generators were used before each field test, to calibrate the field measurement equipment, and after each field test, to validate the proper functioning of the field measurement equipment. For such calibration tests, known amplitudes of electromagnetic energy were inserted into the input of the FIM. This signal substitution was at the operating frequency, pulse rate, and pulse width of the radiation source being tested. All test equipment was certified and was within the normal calibration cycle.

The fiber optics telemetry system used to monitor the pacemaker is designed to present the pacemaker with a load comparable to that produced by the heart, and to prevent EMI pickup in the telemetry link (16). The load network was mounted on a subminiature audio jack to which the pacemaker leads were attached with "flea-clips." A light-emitting diode was mounted in a mating plug so that when the pacemaker fired, approximately one-half of the pacemaker output current passed through the LED, causing it to flash during the pulse. The LED was optically coupled to a length of light pipe which was terminated by a photoresistor in a voltage divider circuit. The output of the voltage divider was amplified by an ECG amplifier and fed to the strip-chart recorder for a permanent record. An electromechanical digital counter in parallel with the recorder was used to numerically determine the pacemaker pulse rate in beats per minute.

To determine whether demand-type pacemakers were operating in their interference-rejection fixed-rate mode or in the normal demand-rate mode, a cardiac simulator system was used to simulate cardiac activity to the pacemaker. This device consists of a variable-frequency pulsating-light source optically coupled via a light pipe and photocell to the pacemaker input leads. If the pacemaker were in its demand mode, the signals from the simulator would, in effect, turn off the pacemaker; if the pacemaker were in the interference-rejection fixed-rate mode, the simulator would have no effect.

The pacemakers were tested in both "free-field" and "simulated-implant" configurations as illustrated in Figure 5. The following paragraphs summarize typical simulated-implant test results by emitter type/function, and frequency. Systems which operate at frequencies greater than 5 GHz are omitted since few, if any, EMI effects were found for such systems.

Height-Finder Radar--Frequency ~2700-2900 MHz; pulse width (duration) ~2 μs; pulse repetition rate ~300-400 pps; peak power ~3-5 MW; scans a -2° to +32° elevation sector with a 3-s-cycle period, often changing its azimuth setting. Dependent on the tower height and terrain elevations, these systems can produce E-field levels of 1000-3000 V/m at distances of 200-2000 ft on the ground in the main beam. However, due to the relatively high operating frequency, short pulse duration, narrow beam width, and the fact that the intense portion of the beam traverses a fixed location rather rapidly, pacemaker interference from these systems is minimal. Characteristically, the more sensitive devices will skip a few beats (5-10 bpm) in close proximity to these systems in the sector scanned by the main beam. Tests conducted using four different height-finder radar over a 2-year period revealed no significant pacemaker interference under simulated-implant conditions.

Search Radar--Frequency ~200-500 MHz; pulse width (duration) ~15-30 μs; pulse repetition rate ~300-400 pps; peak power ~3-5 MW; scans 360° (azimuth) at a fixed elevation angle at 5 rpm. Such systems are usually located on a 50-75 ft tower. They produce a peak E-field level (designated E1) of 150-200 V/m at distances of 500-2500 ft on the ground as the main beam passes overhead. Secondary (E-field level greater than 15° on either side of main beam center) peak E-field levels of 30-80 V/m are typical on the ground at distances of 200-500 ft. The maximum secondary E-field level is designated E2. Many of the pacemakers tested skipped single beats coincident with the passage overhead of the main beam about every 12 seconds, out to distances of about a mile. Closer to these systems where E2 exceeds the threshold of some pacemakers and the moving antenna lobe structure mimics a low PRR, potentially serious pacemaker interference can occur. Most of the adverse effects (significant interference) recorded at distances greater than ~600 ft from these emitters were from pacemaker models that are being rapidly phased out of service and replaced with less sensitive devices.

Search Radar--Frequency ~1250-1350 MHz; pulse width (duration) ~6 μs; repetition rate ~200-400 pps; peak power ~2.5-10 MW; scans 360° (azimuth) at a fixed elevation angle at 5 rpm. These systems are usually located on a 50-75 ft tower. They produce a peak E-field (E1) of 150-400 V/m on the ground at distances of 200-2000 ft as the main beam passes overhead. The E2 levels ranged from 50 to 100 V/m at 150-400 ft distances. These systems affect pacemakers in the same manner as the 200-500 MHz search systems, but the extent of effects is less because of the higher operating frequencies. There was a significant difference in the free-field and simulated-implant data.

Search Radar--Frequency 2400-2900 MHz; operating parameters of these systems are analogous to those of the other search systems except the peak output power may vary over a wider range extending to 15 MW. Peak E-field levels (E1 and E2) of ~150 and 100 V/m, respectively, were recorded at 275 ft. These systems did not produce any significant pacemaker interference in any of these tests, primarily because such systems were located on a 50-75 ft tower and the operating frequency is significantly attenuated by the implant. The same was true for the search systems operating at frequencies greater than 5 GHz.

Ground to Air Telemetry Transmitter--Frequency 250-300 MHz. These systems are capable of 15-20 kW operation, using a fixed omnidirectional antenna (located on a 70 ft pole) to propagate a 33 pps square wave modulated signal. The periods of transmission vary from 2 to 5 s. The pulse periods are separated by 1.5-s intervals during which one or

two pulses of ~35-ms pulse width occur. Although the measured E-field levels did not exceed ~10 V/m, the square wave pulsed signal causes many of the pacemakers to miss up to ~10 bpm within 500 ft of this system. Except for the older more sensitive pacemakers, only one pacemaker, the General Electric model A2075, was significantly affected under the simulated-implant tests.

LORAN-C Transmitter--This system operates at a frequency of 100 kHz, propagating a 9-pulse group repetition rate of 10/s with 1 ms between pulses, and a 250-μs pulse width. An output power of 1 MW is fed to antennas suspended from four 600 ft towers. No significant pacemaker interference was observed from this system, even for tests conducted within 50 ft of the main antenna feed line.

EMP Simulators--Electromagnetic pulse (EMP) simulators are unique sources of RF emission which produce intense pulses (up to 100,000 V/m) in 0.5 μs with ~90% of the frequency components below 10 MHz. Tests were conducted using single pulses at 5, 25, and 50 kV/m. On the basis of pacemaker response recordings made before and after exposure, it was determined the pacemakers were not seriously disrupted. Tests conducted using a repetitively pulsed (2-100 pps) source and peak E-field levels from 300 to 6000 V/m established an EMI threshold of 500 V/m under simulated implant conditions. The effective short pulse probably accounts for the relatively high EMI threshold, although the effect of the EMP frequency spectrum is not well established.

High-Powered Phased Array Surveillance and Track Radar--Frequency 400-450 MHz; pulse widths (duration) up to 60 μs; pulse repetition rates up to 200 pps; peak power 32 MW; about 5000 transmitting elements; RF beam electronically formed and scanned. The RF emission from this type of emitter, producing a series of rapidly varying pulses at essentially all locations on the ground in the primary scan sector, is much different from a normal search radar. Significant pacemaker interference can be expected out to a distance of about 2500 ft.

Multiple-Frequency Emitters--Environmental sites where more than one source of RF emission produces complex E-field patterns are not uncommon. One example is the air route surveillance radar that usually operate in conjunction with one or more height finder radar. Tests conducted under these conditions are difficult to assess, but generally do not appear to represent a significant threat. More complex situations, where perhaps 2-10 different sources are being propagated in the same direction, generally require an empirical evaluation to assess the potential risk to pacemaker users.

Field Tests Summary--The results of these field test studies are summarized as follows:

(1) Many of the pacemakers tested demonstrated some form of periodic interference resulting in reductions in pacemaker rate by 5-6 bpm. From a clinical viewpoint, this type of interference is generally judged insignificant; i.e., the loss of not more than one beat in any 10-s period (13).

(2) EMI thresholds observed in the field tests agree quite well with the data from the laboratory tests.

(3) With the exception of several of the older more sensitive pacemakers, and perhaps one or two current models, there were few examples of serious pacemaker disruption under the simulated-implant conditions in any of these tests.

(4) The potential hazard to pacemaker users in the vicinity of radar complexes has been significantly reduced in the last 2 years with the phaseout of several popular but sensitive model pacemakers, and more importantly, their replacement with new state-of-the-art RF resistant devices.

(5) The results of these field test studies are directly applicable to 90% of the RF emitters in this country today.

DISCUSSION

The laboratory data summarized in Table 1 illustrate the extent to which cardiac pacemaker interference depends on the emission characteristics of the radiation source. Such findings were further substantiated in essentially all the field test studies at RF emitter sites. Additionally, comparison of free-field to simulated-implant test data readily demonstrates that shielding (RF signal attenuation) of both the pacemaker and lead(s) is a major protective factor, particularly at the higher frequencies. This points out that in many cases of pacemaker EMI, the user could effectively eliminate the potential hazard by rotating or relocating his body to increase the shielding between the pacemaker and the source of interference. This may inadvertently happen in many potential interference situations.

Included in these tests were 23 pacemaker models manufactured by 11 different companies. Based on the laboratory tests at 450 MHz, using

a 1-ms pulse duration at 10 pps: (1) 7 of the 23 models tested have EMI thresholds greater than 200 V/m, (2) 10 of 23 have EMI thresholds greater than 100 V/m, (3) 12 of 23 have EMI thresholds greater than 50 V/m, and (4) 8 of the 11 that have EMI thresholds below 50 V/m are older models which are essentially phased out now or will be in the coming months. These test data substantiate the success most manufacturers have had in developing prosthetic devices that are compatible with the electromagnetic environment.

Extrapolation of these field test data to the vast majority of operational RF emitters or emitter complexes in the CONUS reveals few that produce E-field levels (E2) greater than 100 V/m for sufficient time periods to significantly disrupt normal pacemaker function. Thus, if pacemakers were designed and tested to be compatible with the minimum E-field level, viz 200 V/m, associated with the unrestricted 10 mW/cm^2 personnel exposure level, potential EMI situations would be substantially reduced or effectively eliminated. Such actions will eventually achieve overall RF environmental compatibility.

CONCLUSIONS

Cardiac pacemaker EMI is strongly dependent on the frequency, pulse width, real-time E-field level, and effective pulse repetition rate of the incident radiation signal. To a lesser extent but also important is polarization of the field with respect to pacemaker and lead orientation.

Based on the many variables encountered in RF field measurement, implantation simulation, and pacemaker parameters, the reported EMI threshold values can vary by a factor of about 6 dB. Notwithstanding this fact, the values listed in Table 1 are believed most representative of the current state of technology. They can be used as a guide in selecting pacemakers with the better EMI characteristics and/or for assessing potential EMI interactions with a wide range of RF emitters.

Probably the largest variable in assessing the biological impact of pacemaker EMI on man is the heart condition and general state of health of the individual user. A person totally dependent on the pacemaker would obviously suffer greater consequences than one who required only periodic assistance from the pacemaker to regulate heart rate.

Many of the pacemakers included in the field tests, periodically skipped single beats in close proximity to the emitters. However, this is not surprising when one considers this type of pacemaker is designed

to sense the relatively low-level heart signal. These pacemakers undoubtedly respond to many other types of pulsed RF emission in much the same manner. Clinically, this type of EMI is judged insignificant.

On the other hand, pacemakers having EMI thresholds of 100 V/m or less may be expected to encounter serious disruption of normal function in close proximity to certain high-power pulsed emitters.

In general, these current test results, when compared with such studies conducted 2-3 years ago, provide remarkable evidence of the overall improvement in the EMI characteristics of currently marketed cardiac pacemakers. These findings also demonstrate the technical feasibility of manufacturing high-quality RF-resistant pacemakers.

Such improvements will likely continue through the mutual efforts of physicians and manufacturers, recognizing the potential EMI threat in an environment where pulsed-RF sources are commonplace and increasing in number. Also, acceptance of a pacemaker EMC test standard would provide reasonable assurance that all new devices would be compatible with the unrestricted RF environment.

BIBLIOGRAPHY

1. D'Cunha, G. F., et al. Syncopal attacks arising from erratic demand pacemaker function in the vicinity of a television transmitter. Am J Cardiol 31:789-791 (1973).

2. Editorial. Microwaves and pacemakers - just how well do they go together? JAMA 221:957-959 (1972).

3. Hurt, W. D. Effects of electromagnetic interference (2450 MHz) on cardiac pacemakers. SAM-TR-73-40, Dec 1973.

4. Hurt, W. D., et al. Measured effects of square-wave modulated RF fields (450 and 3100 MHz) on cardiac pacemakers. SAM-TR-74-51, Dec 1974.

5. King, G. R., et al. Effect of microwave oven on implanted cardiac pacemakers. JAMA 212:1213 (1970).

6. Koerner, D. R. The employee wearing a cardiac pacemaker. J Occup Med 16:392-394 (1974).

7. Mitchell, J. C., et al. EMC design effectiveness in electronic medical prosthetic devices. Proceedings of the Seventh Rochester International Conference on Environmental Toxicity, Fundamental and Applied Aspects of Non-Ionizing Radiation, University of Rochester, N.Y., 5-7 June 1974.

8. Mitchell, J. C., et al. Empirical studies of cardiac pacemaker interference. Aerospace Med 45(2):189-195 (1974).

9. O'Donoghue, J. K. Inhibition of a demand pacemaker by electrosurgery. Chest 64:664-666 (1973).

10. Pickers, B. A., and M. J. Goldberg. Inhibition of a demand pacemaker and interference with monitoring equipment by radiofrequency transmissions. Br Med J 2:504-506 (1969).

11. Ruggera, P. S., and R. L. Elder. Electromagnetic radiation interference with cardiac pacemakers. U.S. Department of Health, Education and Welfare, PHS, BRH/DEP 71-5, Apr 1971.

12. Sanchez, S. A. When you transmit you can turn off a pacemaker. QST for March 1973.

13. Schlentz, R. J. Electromagnetic compatibility of implanted cardiac pacemakers. Paper presented 20-22 May 1975, EMC Symposium Montreux, Switzerland.

14. Smyth, N. P. D., et al. The pacemaker patient and the electromagnetic environment. JAMA 227:1412 (1974).

15. Sowton, E., K. Gray, and T. Preston. Electrical interference in non-competitive pacemakers. Br Heart J 32:626-632 (1970).

16. Steiner, T. O. Development of a pacemaker monitor with cardiac simulator. SAM-TR-75-7, Feb 1975.

17. Van Wijk Van Brievingh, R. P., et al. Measurement techniques for assessing the influence of electromagnetic fields on implanted pacemakers. Med Biol Eng 12(1):42-48 (1974).

18. Walter, W. H., III, et al. Cardiac pulse generators and electromagnetic interference. JAMA 224:1628-1631 (1973).

ABBREVIATIONS AND ACRONYMS

AV	atrioventricular
bpm	beats per minute
cm	centimeter(s)
CW	continuous wave
dB	decibel(s)
E-field	electric field strength (V/m)
EMI	electromagnetic radiation interference
EMR	electromagnetic radiation
Hz	hertz
kHz	kilohertz
LED	light-emitting diode
MHz	megahertz
μs	microsecond(s)
ms	millisecond(s)
mW	milliwatt(s)
MW	megawatt(s)
pps	pulse(s) per second
PRR	pulse repetition rate
PW	pulse width
RF	radiofrequency
rms	root mean square
s	second
V/m	volt(s) per meter